510(k) Summary

APR 0 5 2013

510(k) SPONSOR / MANUFACTURER: Custom Orthopaedic Solutions, Inc.
A subsidiary of Cleveland Clinic
10000 Cedar Avenue
Cleveland, Ohio 44106

CONTACT PERSON: Stephen J. Peoples, VMD, MS
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TRADE NAME: Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)

COMMON NAMES: Total shoulder replacement instruments

Product	Product Code	Regulation and Classification Name	Device Class
Glenoid Reusable Intelligent Instrument System (Glenoid IRIS)	**KWS**	**21 CFR 888.3660 Shoulder, semi-constrained metal / polymer, cemented**	**II**

PREDICATE DEVICES:

DePuy Global Shoulder AP Shoulder System (K060874
DePuy Global Shoulder Glenoid (K981487)
DePuy Global StepTech Anchor Peg Glenoid (K092122)
DePuy Delta Xtend Reverse Shoulder System (062250)

DEVICE DESCRIPTION:

The **Glenoid Intelligent Reusable Instrument System** is composed of two (2) manual instruments intended for use to facilitate preoperative planning and intraoperative placement of the glenoid component in total shoulder replacement. CT data and 3D modeling is used to provide preoperative planning of total shoulder glenoid component or reverse shoulder metaglene component orientation according to each patient's glenoid anatomy. The preoperatively planned and surgeon approved component orientation is subsequently transferred to the patient's glenoid during surgery by the use of a patient specific instrument and an adjustable reusable instrument with patient specific settings. A patient specific **Glenoid SmartBone – Pin Trajectory** instrument is used to set the adjustable reusable instrument, the **Glenoid Intelligent Reusable Instrument (Glenoid IRI),** with the settings necessary to reflect the guide pin trajectory embedded in the Glenoid SmartBone. The Glenoid IRI is then used to guide the placement of the standard 2.5 mm pin (Steinmann pin) by the surgeon that is used in preparation of the glenoid for implantation of the glenoid component. All other steps of the surgical procedure are accomplished according to each system's standard surgical technique.

INTENDED USE AND INDICATIONS:

The **Glenoid Intelligent Reusable Instrument System** (**"Glenoid IRIS"**) is a patient specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Glenoid IRIS is indicated for use in planning and placing the central glenoid guide pin for the DePuy Anchor Peg Glenoid (APG) component of the DePuy AP Shoulder System, the DePuy Global StepTech Glenoid component, or the DePuy Delta Xtend Reverse Shoulder metaglene component as an alternative to the standard instruments provided for placing the guide pin with these implant systems. The Glenoid IRIS is not indicated for use in hemi-shoulder arthroplasty.

The labeling and indications for use for each of these DePuy shoulder systems remain the same as described in DePuy's labeling.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The **Glenoid Intelligent Reusable Instrument System** (**"Glenoid IRIS"**) is intended to be used as an alternative method and instrument system for placing the 2.5 mm glenoid guide pin that is used for preparing the glenoid for implantation with the DePuy Global AP Shoulder Glenoid component, the DePuy Global StepTech Anchor Peg Glenoid component, or the DePuy Delta Xtend Reverse Shoulder System metaglene component. The **Glenoid IRIS** replaces the standard instruments and techniques for the placement of the guide pin in these systems as described in each system's surgical technique. The **Glenoid IRIS** has the same intended use and indications for use and similar function, surgical technique, design, materials, and performance as the standard instruments used for placing the glenoid guide pin in these systems. All other surgical steps are completed according to the steps described in the surgical techniques for each system using the standard instruments supplied for each system. The indications for use of the DePuy shoulder systems, with which the Glenoid IRIS is intended to be used, are not changed by the Glenoid IRIS and remain the same as described in the labeling for these shoulder systems.

Non-Clinical Testing

The following testing was performed to demonstrate substantial equivalency of the Glenoid IRIS to the predicate devices.

- Performance testing - verification and validation testing
- Performance testing - biocompatibility and toxicity (ISO 10993-10; USP Class VI)
- Performance testing - cadaver study
- Performance testing - sawbones study
- Performance testing - software validation
- Performance testing - packaging integrity testing

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence between the Glenoid IRIS and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Custom Orthopaedic Solutions, Inc.
A subsidiary of Cleveland Clinic
c/o Stephen J. Peoples, VMD, MS
Peoples & Associates Consulting, LLC
5010 Lodge Pole Lane
Fort Wayne, IN, 46814

Letter dated: April 5, 2013

Re: K123122
Trade/Device Name: Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: March 11, 2013
Received: March 14, 2013

Dear Dr. Peoples,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123122

Device Name: Glenoid Intelligent Reusable Instrument System

Intended Use and Indications for Use:

The **Glenoid Intelligent Reusable Instrument System** ("**Glenoid IRIS**") is a patient specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Glenoid IRIS is indicated for use in planning and placing the central glenoid guide pin for the DePuy Anchor Peg Glenoid (APG) component of the DePuy AP Shoulder System, the DePuy Global StepTech Glenoid component, or the DePuy Delta Xtend Reverse Shoulder metaglene component as an alternative to the standard instruments provided for placing the guide pin with these implant systems. The Glenoid IRIS is not indicated for use in hemi-shoulder arthroplasty.

The labeling and indications for use for each of these DePuy shoulder systems remain the same as described in DePuy's labeling.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) page 1 of 1

Elizabeth D. Frank -S

Division of Orthopedic Devices